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(54) APPARATUS FOR PERFORMING CORONARY ARTERY BYPASS SURGERY

VORRICHTUNG ZUR DURCHFÜHRUNG EINER KORONAREN ARTERIENBYPASSOPERATION

APPAREIL POUR REALISER UN PONTAGE AORTOCORONARIEN

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention.

[0001] The present invention relates generally to an apparatus for performing a coronary artery bypass procedure. More particularly, the present invention performs a coronary artery bypass by providing a direct flow path from a heart chamber to the coronary artery. The present invention is suitable for a number of approaches including an open-chest approach (with and without cardiopulmonary bypass), a closed-chest approach under direct viewing and/or indirect thoracoscopic viewing (with and without cardiopulmonary bypass), and an internal approach through catheterization of the heart and a coronary arterial vasculature without direct or indirect viewing (with and without cardiopulmonary bypass).

2. Description of the Prior Art.

A. Coronary Artery Disease

[0002] Coronary artery disease is the leading cause of premature death in industrialized societies. The mortality statistics tell only a portion of the story. Many who survive face prolonged suffering and disability.

[0003] Arteriosclerosis is "a group of diseases characterized by thickening and loss of elasticity of arterial walls." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 137 (27th ed. 1988). Arteriosclerosis "comprises three distinct forms: atherosclerosis, Monckeberg's arteriosclerosis, and arteriolosclerosis." *Id.*

[0004] Coronary artery disease has been treated by a number of means. Early in this century, the treatment for arteriosclerotic heart disease was largely limited to medical measures of symptomatic control. Evolving methods of diagnosis, coupled with improving techniques of post-operative support, now allow the precise localization of the blocked site or sites and either their surgical re-opening or bypass.

B. Angioplasty

[0005] The re-opening of the stenosed or occluded site can be accomplished by several techniques. Angioplasty, the expansion of areas of narrowing of a blood vessel, is most often accomplished by the intravascular introduction of a balloon-equipped catheter. Inflation of the balloon causes mechanical compression of the arteriosclerotic plaque against the vessel wall.

[0006] Alternative intravascular procedures to relieve vessel occlusion include atherectomy, which results in the physical desolution of plaque by a catheter equipped with a removal tool (e.g., a cutting blade or high-speed rotating tip). Any of these techniques may or may not be followed by the placement of a mechanical support (i.e., a stent) which physically holds open the artery.

[0007] Angioplasty, and the other above-described techniques (although less invasive than coronary artery bypass grafting) are fraught with a correspondingly greater failure rate due to intimal proliferation. Contemporary reports suggest re-stenosis is realized in as many as 25 to 55 percent of cases within 6 months of successful angioplasty. *See* Bojan Cercek et al., 68 AM. J. CARDIOL. 24C-33C (Nov. 4, 1991). It is presently believed stenting can reduce the re-stenosis rate.

[0008] A variety of approaches to delay or prevent re-blockage have evolved. One is to stent the site at the time of balloon angioplasty. Another is pyroplasty, where the balloon itself is heated during inflation. As these alternative techniques are relatively recent innovations, it is too early to tell just how successful they will be in the long term. However, because re-blockage necessitates the performance of another procedure, there has been renewed interest in the clearly longer-lasting bypass operations.

C. Coronary Artery Bypass Grafting

i. Outline of Procedure

[0009] The traditional open-chest procedure for coronary artery bypass grafting requires an incision of the skin anteriorly from nearly the neck to the navel, the sawing of the sternum in half longitudinally, and the spreading of the ribcage with a mechanical device to afford prolonged exposure of the heart cavity. If the heart chamber or a vessel is opened, a heart-lung, or cardiopulmonary bypass, procedure is usually necessary.

[0010] Depending upon the degree and number of coronary vessel occlusions, a single, double, triple, or even greater number of bypass procedures may be necessary. Often each bypass is accomplished by the surgical formation of a separate conduit from the aorta to the stenosed or obstructed coronary artery at a location distal to the diseased site.

ii. Limited Number of Available Grafts

[0011] The major obstacles to coronary artery bypass grafting include both the limited number of vessels that are available to serve as conduits and the skill required to effect complicated multiple vessel repair. Potential conduits include the two saphenous veins of the lower extremities, the two internal thoracic (mammary) arteries under the sternum, and the single gastroepiploic artery in the upper abdomen.

[0012] Newer procedures using a single vessel to bypass multiple sites have evolved This technique has its own inherent hazards. When a single vessel is used to perform multiple bypasses, physical stress(e.g., torsion) on the conduit vessel can result. Such torsion is particularly detrimental when this vessel is an artery. Unfortunately, attempts at using artificial vessels or vessels

from other species (xenografts), or other non-related humans (homografts) have been largely unsuccessful. *See* LUDWIG K. VON SEGESSER, ARTERIAL GRAFTING FOR MYOCARDIAL REVASCULARIZATION: INDICATIONS, SURGICAL TECHNIQUES AND RESULTS 38-39 (1990).

[0013] While experimental procedures transplanting alternative vessels continue to be performed, in general clinical practice, there are five vessels available to use in this procedure over the life of a particular patient. Once these vessels have been sacrificed or affected by disease, there is little or nothing that modern medicine can offer. It is unquestionable that new methods, not limited by the availability of such conduit vessels, are needed.

iii. Trauma of Open Chest Surgery

[0014] In the past, the normal contractions of the heart have usually been stopped during suturing of the bypass vasculature. This can be accomplished by either electrical stimulation which induces ventricular fibrillation, or through the use of certain solutions, called cardioplegia, which chemically alter the electrolyte milieu surrounding cardiac muscles and arrest heart activity.

[0015] Stoppage of the heart enhances visualization of the coronary vessels and eliminates movement of the heart while removing the need for blood flow through the coronary arteries during the procedure. This provides the surgeon with a "dry field" in which to operate and create a functional anastomosis.

[0016] After the coronary artery bypass procedure is completed, cardioplegia is reversed, and the heart electrically stimulated if necessary. As the heart resumes the systemic pumping of blood, the cardiopulmonary bypass is gradually withdrawn. The separated sternal sections are then re-joined, and the overlying skin and saphenous donor site or sites (if opened) are sutured closed.

[0017] The above-described procedure is highly traumatic. Immediate post-operative complications include infection, bleeding, renal failure, pulmonary edema and cardiac failure. The patient must remain intubated and under intensive post-operative care. Narcotic analgesia is necessary to alleviate the pain and discomfort.

iv. Post-Operative Complications

[0018] Once the immediate post-surgical period has passed, the most troubling complication is bypass vessel re-occlusion. This has been a particular problem with bypass grafting of the left anterior descending coronary artery when the saphenous vein is employed.

[0019] Grafting with the internal thoracic (internal mammary) artery results in a long-term patency rate superior to saphenous vein grafts. This is particularly the case when the left anterior descending coronary artery is bypassed. Despite this finding, some cardiothoracic surgeons continue to utilize the saphenous vein because the internal thoracic artery is smaller in diameter and more fragile to manipulation. This makes the bypass more complex, time-consuming, and technically difficult. Additionally, there are physiological characteristics of an artery (such as a tendency to constrict) which increase the risk of irreversible damage to the heart during the immediate period of post-surgical recovery.

[0020] Once the patient leaves the hospital, it may take an additional five to ten weeks to recover completely. There is a prolonged period during which trauma to the sternum (such as that caused by an automobile accident) can be especially dangerous. The risk becomes even greater when the internal thoracic artery or arteries, which are principle suppliers of blood to the sternum, have been ligated and employed as bypass vessels.

v. Less Invasive Procedures

[0021] Due to the invasive nature of the above technique, methods have been devised which employ contemporary thoracoscopic devices and specially-designed surgical tools to allow coronary artery bypass grafting by closed-chest techniques. While less invasive, all but the most recent closed-chest techniques still require cardiopulmonary bypass, and rely on direct viewing by the surgeon during vascular anastomoses.

[0022] These methods require a very high level of surgical skill together with extensive training. In such situations, the suturing of the bypassing vessel to the coronary artery is performed through a space created in the low anterior chest wall by excising the cartilaginous portion of the left fourth rib. Also, as they continue to rely on the use of the patient's vessels as bypass conduits, the procedures remain limited as to the number of bypasses which can be performed. Because of these issues, these methods are not yet widely available.

vi. Objectives for Improved Bypass Procedures

[0023] In view of the above, it is desirable to provide other methods by which adequate blood flow to the heart can be re-established and which do not rely on the transposition of a patient's own arteries or veins. Preferably, such methods will result in minimal tissue injury.

[0024] While the attainment of the foregoing objectives through an open chest procedure would, by themselves, be a significant advance, it is also desirable if such methods would also be susceptible to surgical procedures which do not require opening of the chest by surgical incision of the overlying skin and the division of the sternum. Such methods would not require surgical removal of cartilage associated with the left fourth rib, would not require the surgical transection of one or both internal thoracic arteries, would not require the surgical incision of the skin overlying one or both lower extremities, and would not require the surgical transection and

removal of one or both saphenous veins. In both an open and closed chest approach, it is also be desirable if such methods could be performed without stoppage of the heart and without cardiopulmonary bypass. However, attainment of the foregoing objectives in a procedure requiring cardiopulmonary bypass would still be a significant advance in the art.

vii. References for Prior Art Techniques

[0025] The conventional surgical procedures (such as those described above) for coronary artery bypass grafting using saphenous vein or internal thoracic artery via an open-chest approach have been described and illustrated in detail. *See generally* Stuart W. Jamieson, *Aortocoronary Saphenous Vein Bypass Grafting, in* ROB & SMITH'S OPERATIVE SURGERY: CARDIAC SURGERY, 454-470 (Stuart W. Jamieson & Norman E. Shumway eds., 4th ed. 1986); LUDWIG K. VON SEGESSER, ARTERIAL GRAFTING FOR MYOCARDIAL REVASCULARIZATION: INDICATIONS, SURGICAL TECHNIQUES AND RESULTS 48-80(1990). Conventional cardiopulmonary bypass techniques are outlined in Mark W. Connolly & Robert A. Guyton, *Cardiopulmonary Bypass Techniques, in* HURST'S THE HEART 2443-450 (Robert C. Schlant & R. Wayne Alexander eds., 8th ed. 1994). Coronary artery bypass grafting utilizing open-chest techniques but without cardiopulmonary bypass is described in Enio Buffolo et al., *Coronary Artery Bypass Grafting Without Cardiopulmonary Bypass*, 61 ANN. THORAC. SURG. 63-66 (1996).

[0026] Some less conventional techniques (such as those described above) are performed by only a limited number of appropriately skilled practitioners. Recently developed techniques by which to perform a coronary artery bypass graft utilizing thoracoscopy and minimally-invasive surgery, but with cardiopulmonary bypass, are described and illustrated in Sterman et al., U.S. Patent No. 5,452,733 (1995). An even more recent coronary artery bypass procedure employing thoracoscopy and minimally-invasive surgery, but without cardiopulmonary bypass, is described and illustrated by Tea E. Acuff et al., *Minimally Invasive Coronary Artery Bypass Grafting*, 61 ANN. THORAC. SURG. 135-37 (1996).

D. Bypass With Direct Flow From Left Ventricle

1. Summary of Procedures

[0027] Certain methods have been proposed to provide a direct blood flow path from the left ventricle directly through the heart wall to the coronary artery. These are described in U.S. Patent Nos. 5,429,144 dated July 4, 1995; 5,287,861 dated February 22, 1994; and 5,409,019 dated April 25, 1995 (all to Wilk). All of these techniques include providing a stent in the heart wall to define a direct flow path from the left ventricle of the heart to the coronary artery.

[0028] As taught in each of the above-referenced patents, the stent is closed during either systole or diastole to block return flow of blood from the coronary artery during the heart's cycle. For example, the '861 patent teaches a stent which collapses to a closed state in response to heart muscle contraction during systole. The '019 patent (particularly Figs. 7A and 7B) teaches a rigid stent (i.e., open during systole) with a one-way valve which closes during diastole to block return flow of blood from the coronary artery.

ii. Problems

[0029] The interruption of blood flow during either diastole or systole is undesirable since such interruption can result in areas of stagnant or turbulent blood flow. Such areas of stagnation can result in clot formation which can result in occlusion or thrombi breaking lose. Such thrombi can be carried to the coronary arteries causing one or more areas of cardiac muscle ischemia (myocardial infarction) which can be fatal. Further, the teachings of the aforementioned patents direct blood flow with a substantial velocity vector orthogonal to the axis of the coronary artery. Such flow can damage the wall of the coronary artery.

[0030] Providing direct blood flow from the left ventricle of the coronary artery has been criticized. For example, Munro et al., *The Possibility of Myocardial Revascularization By Creation of a Left Ventriculocoronary Artery Fistula*, 58 Jour. Thoracic and Cardiovascular Surgery, 25-32 (1969) shows such a flow path in Fig. 1. Noting a fall in coronary artery flow and other adverse consequences, the authors concluded "that operations designed to revascularize the myocardium direct from the cavity of the left ventricle make the myocardium ischemic and are unlikely to succeed." Id at 31.

[0031] Notwithstanding the foregoing problems and scholarly criticism, and as will be more fully described, the present invention is directed to an apparatus and method for providing a direct blood flow path from a heart chamber to a coronary artery downstream of an obstruction. Counter to the teachings of the prior art, the present invention provides substantial net blood flow to the coronary artery.

E. Additional Techniques

[0032] Methods of catheterization of the coronary vasculature, techniques utilized in the performance of angioplasty and atherectomy, and the variety of stents in current clinical use have been summarized. *See generally* Bruce F. Waller & Cass A. Pinkerton, *The Pathology of Interventional Coronary Artery Techniques and Devices, in* 1 TOPOL'S TEXTBOOK OF INTERVENTIONAL CARDIOLOGY 449-476 (Eric J. Topol ed., 2nd ed. 1994); *see also* David W. M. Muller & Eric J. Topol, *Overview of Coronary Athrectomy, in* 1 TOPOL'S TEXTBOOK OF INTERVENTIONAL CARDIOLOGY at

678-684; *see also* Ulrich Sigwart, *An Overview of Intravascular Stents: Old & New, in* 2 TOPOL'S TEXTBOOK OF INTERVENTIONAL CARDIOLOGY at 803-815.

[0033] Direct laser canalization of cardiac musculature (as opposed to canalization of coronary artery feeding the cardiac musculature) is described in Peter Whittaker et al., *Transmural Channels Can Protect Ischemic Tissue: Assessment of Long-term Myocardial Response to Laser- and Needle-Made Channels*, 94(1) CIRCULATION 143-152 (Jan. 1, 1996). Massimo et al., *Myocardial Revascularization By a New Method of Carrying Blood Directly From The Left Ventricular Cavity Into The Coronary Circulation,* 34 Jour. Thoracic Surgery 257-264 (1957) describes a T-shaped tube placed within the ventricular wall and protruding into the cavity of the left ventricle. Also, Vineberg et al., *Treatment of Acute Myocardial Infarction By Endocardial Resection,* 57 Surgery 832-835 (1965) teaches forming a large opening between the left ventricular lumen and the sponge-like network of vessels lying within the myocardium.

SUMMARY OF THE INVENTION

[0034] According to the present invention, an apparatus for surgically bypassing an obstructed coronary artery establishes a channel leading directly from a chamber of the heart into the obstructed coronary artery at a site distal to the obstruction and holding the channel open during both systole and diastole. Additionally, the apparatus of the invention avoids impingement of high velocity blood flow directly against the coronary artery wall.

[0035] The present invention is particularly useful for coronary artery bypass procedures in a patient suffering from obstructive coronary artery disease. The present invention permits an array of procedures of varying invasiveness.

[0036] The present invention avoids the previous limitations on the number of performable bypass procedures. Due to the limited number of arteries and/or veins available, standard procedures become increasingly risky to repeat. Rather than relying on harvested veins and arteries as bypass conduits, the present invention forms a channel (or conduit) which leads directly from a chamber of a patient's heart into a coronary artery at a site distal to the obstruction or narrowing.

[0037] In the most preferred embodiment, the left ventricle is the chamber of the heart utilized. There are two reasons for this selection. First, the left ventricle normally provides blood to the coronary arteries, because it pumps blood into the aorta from which the coronary arteries branch. Therefore, the magnitude of the blood pressure peak generated by the left ventricle is most similar to the blood pressure peak the proximal coronary artery would normally experience. Second, the blood which flows into the left ventricle is returning from the lungs. In the lungs, the blocd acquires oxygen and loses carbon dioxide. Thus, the blood available by shunting from the chambers of the left side of the heart will have a higher oxygen and lower carbon dioxide content then blood within the right-side heart chambers.

BRIEF DESCRIPTION OF THE DRAWINGS

[0038]

FIG. 1A is a right, front and top perspective view of an L-shaped conduit for use in the present invention;

FIG. 1B is a side elevation view of the apparatus of **FIG. 1A** shown partially in section to reveal an optional bi-directional flow regulator located in a lumen of an anchor arm of the conduit;

FIG. 2A is a right, front and top perspective view of a T-shaped conduit which is not covered by the present invention as claimed herein but is contained to illustrate details useful for the understanding of the present invention, like the flow regulator.

FIG. 2B is a side elevation view of the conduit of **FIG. 2A** shown partially in section to reveal an optional bi-directional flow regulator located in a lumen of an anchor arm of the conduit;

FIG. 2C is a side elevation view of the conduit of **FIG. 2A** shown partially in section to reveal one optional bi-directional flow regulator located in the lumen of the anchor arm of the conduit, and another optional bi-directional flow regulator located in an intracoronary arm of the conduit;

FIG. 3 is an anterior view of a human chest which is incised longitudinally to reveal a dissected pericardium and mediastinal contents;

FIG. 4 is a magnified view of an area circled **200** in **FIG. 3** illustrating a longitudinally incised coronary artery;

FIG. 5 is a partial external perspective view of a transversely sectioned coronary artery and heart wall illustrating a channel leading from a lumen of a coronary artery and into a chamber of the heart according to the method of the present invention;

FIG. 6 is a partial external perspective view of a transversely sectioned coronary artery and heart wall illustrating the partial placement of one embodiment of the conduit of the present invention into the incised coronary artery and formed channel illustrated in **FIG. 5;**

FIG. 7 is a partial external perspective view of a transversely sectioned coronary artery and heart wall illustrating the completed placement of one embodiment of the conduit of the present invention into the incised coronary artery and formed channel illustrated in **FIG. 5;**

FIG. 8 is a partial external perspective view of a sutured coronary artery and phantom view of the conduit of the present invention;

FIG. 9A is a schematic longitudinal cross-sectional

view of a bi-directional flow regulator shown in a full flow position.

FIG. 9B is the view of **FIG. 9A** with the bi-directional flow regulator shown in a reduced flow position;

FIG. 9C is a transverse cross-sectional view of the bi-directional flow regulator of **FIG. 9B**;

FIG. 10A is a schematic cross-section longitudinal view of an alternative embodiment of a bi-directional flow regulator shown in a full flow position;

FIG. 10B is the view of **FIG. 10A** showing the bi-directional flow regulator in a reduced flow position;

FIG. 10C is a transverse cross-sectional view of the bi-directional flow regulator of **FIG. 10B**;

FIG. 11 is a schematic longitudinal cross-sectional view of a channel defining conduit not coveredd by this invention as claimed herein but useful to illustrate details thereof, like tapered anchor arm;

FIG. 12 is a schematic longitudinal cross-sectional view of the conduit of **FIG. 1A** in place in a coronary artery;

FIG. 13 is a schematic longitudinal cross-sectional view of a test conduit for animal testing of the invention; and

Fig. 14 is a schematic longitudinal cross-sectional view of a conduit in place in a coronary artery illustrating a deflecting shield to protect the coronary artery.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0039] With reference now to the various drawing figures in which identical elements are numbered identically throughout, a description of the preferred embodiment of the present invention and various alternative embodiments will now be provided.

A. Detailed Summary of the Preferred Embodiment

[0040] The invention departs from the traditional bypass approach. Rather then providing an alternative pathway for blood to flow from an aorta to a coronary artery, the invention provides a blood flow path leading directly from a chamber of a heart to a coronary artery at a site downstream from the stenosis or occlusion. Unlike U.S. Patent Nos. 5,429,144; 5,287,861 and 5,409,019 and contrary to the teachings of these patents, the ventricular-to-coronary artery blood flow path remains open during both diastole and systole. The surgical placement of the apparatus of the present invention establishes this alternative pathway. Also, and as will be more fully described, the invention includes means for protecting the coronary artery from direct impingement of high velocity blood flow.

[0041] While the invention will be described in multiple embodiments and with the description of various surgical procedures for practicing the invention, it will be appreciated that the recitation of such multiple embodiments is done for the purpose of illustrating non-limiting examples of multiple forms which the present invention may take.

[0042] The presently preferred embodiment is illustrated in **FIG. 1A** as an L-shaped conduit **10'** with an intracoronary arm **14'** to reside in the coronary artery (and opening downstream of an occlusion). The conduit **10'** has an anchor arm **12'** extending through the heart wall with an opening **12a'** in communication with the interior of the left ventricle.

[0043] While various minimally invasive surgical procedures are described with respect to alternative embodiments, the presently preferred embodiment places the conduit **10'** into a coronary artery through an open-chest approach to be described in greater detail with reference to **FIGS. 3 - 8.** While minimally invasive procedures are desirable, an open chest procedure is presently preferred due to the already large number of physicians trained and skilled in such procedures thus making the benefits of the present invention more rapidly available to patients who currently lack effective treatment.

[0044] While the various embodiments (including the presently preferred embodiment of **FIG. 1A**) will be described in greater detail, a preliminary description of the invention and of a method of using it will now be given with reference to **FIG. 12** to facilitate an understanding of a detailed description of the invention and the alternate embodiments.

[0045] **FIG. 12** is a schematic cross-sectional view of a conduit **10'** of **FIG. 1A** placed within a coronary artery **30.** Coronary artery **30** has a lower surface **40** residing against an external surface of a heart wall **42** surrounding the left ventricle **44.**

[0046] The wall **36** of the artery **30** defines an artery lumen **48** through which blood flows in the direction of arrow **A.** In the view of **FIG. 12,** an obstruction **34** is shown within the lumen **48.** The obstruction **34** acts to reduce the volume of blood flow along the direction of arrow **A.**

[0047] The conduit **10'** is a rigid, L-shaped tube having an anchor arm **12'** with a longitudinal axis X-X and an opening **12a'** at an axial end,

[0048] The conduit **10'** has an intracoronary arm **14'** with a longitudinal axis **Y-Y** and an opening **14a'** at an axial end. Both of arms **12', 14'** are cylindrical in shape and define a continuous blood flow pathway **11'** from opening **12a'** to opening **14a'.**

[0049] The axes **X-X** and **Y-Y** are perpendicular in a preferred embodiment. Alternatively, the axes **X-X, Y-Y** could define an angle greater than 90° to provide a less turbulent blood flow from arm **12'** to arm **14'.**

[0050] The conduit 10' is positioned for the anchor arm **12'** to pass through a preformed opening **50** in the heart wall **42** and extending from the lower surface **40** of the coronary artery **30** into the left ventricle **44.** The opening **12a'** is in blood flow communication with the interior of the left ventricle **44** so that blood may flow from the left ventricle **44** directly into path **11'.** The arm

14' is coaxially aligned with the coronary artery 30 and with the opening 14a' facing downstream (i.e., in a direction facing away from obstruction 34).

[0051] Blood flow from opening 12a' passes through the pathway 11' and is discharged through opening 14a' into the lumen 48 of the coronary artery 30 downstream of the obstruction 34. The outer diameter of arm 14a' is approximate to or slightly less than the diameter of the lumen 48.

[0052] The axial length of the anchor arm 12' is greater than the thickness of the heart wall 42 such that a length L protrudes beyond the interior surtace of the heart wall 42 into the left ventricle 44. Preferably, the length L of penetration into the left ventricle 44 is about 1-3 millimeters in order to prevent tissue growth and occlusions over the opening 12a'.

[0053] In addition to directing blood flow downstream in the direction of arrow A, the arm 14' holds the conduit 10' within the coronary artery 30 to prevent the conduit 10' from otherwise migrating through the preformed opening 50 and into the left ventricle 44. Additionally, an upper wall 14b' of arm 14' defines a region 15' against which blood flow may impinge. Stated differently, in the absence of an arm 14' or region 15', blood flow would pass through the anchor arm 12' and impinge directly against the upper wall 36 of the coronary artery 30. High velocity blood flow could damage the wall 36, as will be more fully described, resulting in risk to the patient.

[0054] The region 15' acts as a shield to protect the coronary artery 30 from such blood flow and to redirect the blood flow axially out of opening 14a' into the coronary artery 30. This is schematically illustrated in Fig. 14. For ease of illustration, the axis X-X of the anchor arm 12' is shown at a non-orthogonal angle with respect to the direction A of blood flow in the coronary artery 30 (axis X-X may be either orthogonal or non-orthogonal to direction A). The vector B of blood flow from the anchor arm 12' has a vector component B' parallel to blood flow A and a vector component B" perpendicular to direction A. The region 15' is positioned between the wall 36 and anchor arm 12' to prevent the blood flow B with high vector component B" from impinging upon wall 36. The blood flow deflected off region 15' has a reduced vector component perpendicular to flow direction A and reduced likelihood of damage to the coronary artery 30.

[0055] A portion 17' of the anchor arm 12' extends from the lower surface 40 of the coronary artery 30 and through the lumen 48 to the upper surface 36 to block the cross-section of the coronary artery upstream from opening 14a'. The region 17' acts as a barrier to impede or prevent any dislodged portions of the obstruction 34 from passing the conduit 10' and flowing downstream through the coronary artery 30.

[0056] The present invention maintains blood flow through the conduit 10' during both diastole and systole. Therefore, while the net blood flow is in the direction of arrow A, during diastole, blood will flow in a direction opposite of that of arrow A.

[0057] The constantly open pathway 11' results in a net flow in the direction of arrow A which is extraordinarily high and sufficient to reduce or avoid patient symptoms otherwise associated with an obstruction 34. Specifically, certain aspects of the apparatus and method of the present invention have been preliminary tested in animal studies. FIG. 13 schematically illustrates the tests as the placement of a test conduit 10* in the coronary artery 30' of a pig. For purposes of the tests, a stainless steel T-shaped conduit 10* not covered by the invention as claimed herein but useful to illustrate details thereof is used having aligned openings 14a*, 16a* positioned within the coronary artery 30' and with a third opening 12a* protruding 90° out of the coronary artery 30'. The conduit 10* has a uniform interior diameter of 3 millimeters to correspond in sizing with a 3 millimeter lumen of coronary artery 30'. The third opening 12a* is connected by a 3 millimeter conduit 13 to a 3 millimeter rigid Teflon (PTFE) sleeve 13a which was passed through the heart wall 42' into the left ventricle 44'. The conduit 13 and sleeve 13a do not pass through the coronary artery 30'.

[0058] [n the view of FIG. 13, the direction of net blood flow is shown by arrow A. A first closure device in the form of a suture loop 300 surrounds the artery 30' adjacent the upstream opening 14a* of the conduit 10*. The loop 300 provides a means for closing the upstream opening 14a* by selectively constricting or opening the loop 300 to selectively open or block blood flow through the coronary artery 30'. The first loop 300 permits the test to simulate blockage of the coronary artery 30' upstream of the conduit 10*.

[0059] A flow meter 304 to measure volumetric flow of blood downstream of the conduit 10* is placed adjacent downstream opening 16a*. A second closure device 302 functioning the same as loop 300 is placed on conduit 13 to selectively open or close blood flow through conduit 13.

[0060] When the second device 302 is closed and the first device 300 is open, the conduit 10* simulates normal blood flow through a healthy coronary artery 30' and the normal blood flow can be measured by the flow measuring device 304. By opening second device 302 and closing the first device 300, the test conduit 10* can simulate the placement of a conduit such as that in FIG. 21 with an obstruction located on the upstream side of the conduit. The flow meter 304 can then measure flow of blood through the conduit 10* during both diastole and systole.

[0061] The results of the tests indicate there is a substantial net forward blood flow (i.e., volumetric forward flow less volumetric retro-flow) with the second device 302 remaining open during both diastole and systole and with the first device 300 closed to simulate an obstruction. Specifically, in the tests, net blood flows in excess of 80 percent of normal net forward blood flow were measured. It was also noted that with the second device 302 closed and first device 300 open to simulate normal

blood flow, the peak blood flow through the coronary artery **30'** occurred during systole. With the first device **300** closed to simulate an obstruction and with the second device **302** open, the peak blood flow occurred at diastole.

[0062] The amount of back flow through a conduit can be controlled without the need for providing a valve within the conduit. Conveniently referred to as flow "bias", a volumetric forward flow greater than a volumetric rearward flow can be manipulated through a variety of means including sizing of the interior diameter of the conduit, geometry of the conduit (e.g., taper, cross-sectional geometry and angle) and, as will be more fully discussed, structure to restrict rear flow relevant to forward flow.

[0063] The sizing of the interior diameter of the flow pathway **11'** can be selected to minimize back flow. As will be more further discussed, the net flow increases with a reduction in the diameter as suggested by simulation modeling of flow through a conduit. One method in which shear rate and flow bias can be controlled is by providing a tapered diameter for a narrower diameter at opening **14a'** than at opening **12a'**. The selection of the conduit geometry (e.g., an angled anchor arm as shown in **Fig. 14** or a tapered geometry as will be discussed with reference to **Fig. 11**) can be selected to modify the degree to which the conduit is biased to net forward flow (i.e., the conduit offers less resistance to foward flow than to retro-flow) without stopping or blocking retro-flow.

[0064] The substantial net blood flow measured in animal testing through the invention is extraordinarily high when compared to minimum acceptable levels of net blood flow following traditional bypass techniques (i.e., about 25 percent of normal net blood flow). Further, the results are counter-intuitive and contradictory to the prior teachings of the art of U.S. Patent Nos. 5,429,144; 5,287,861 and 5,409,919 and the afore-mentioned Munro et al. article. In addition, the present invention provides a conduit with a shielding area to prevent damaging impingement of blood flow directly onto the coronary artery wall as well as providing a blocking area to prevent the migration of debris from an obstruction to a location downstream of the conduit.

[0065] Having provided a summarized version of the present invention with reference to the schematic drawings of **FIGS. 12** and **13**, a more detailed description of the present invention as well as a detailed description of alternative embodiments and alternative surgical procedures will now be provided.

B. Embodiments with an Open Chest Approach

1. The Apparatus of the Present Invention for Use in the Open Chest Approach

[0066] As will be more fully described, the present invention places an apparatus for defining a blood flow conduit directly from a chamber of a heart to a coronary artery downstream of an occluded site. Before describing the surgical methods for placing such an apparatus, an apparatus of the present invention will be described.

T-Shaped Device

[0067] With initial reference to **FIGS. 2A, 2B** and **2C**, devices are shown as a rigid T-shaped conduit **10** which are not covered by the invention as claimed herein but are useful to illustrate details thereof, like the flow regulator in this case (the L-shaped conduit **10'** of the invention having already been summarized and to be later described in detail). The conduit **10** is hollow and includes two axially-aligned intracoronary arms **14, 16** terminating at open ends **14a, 16a.** An anchor arm **12** (having an open end **12a**) extends perpendicularly to arms **14, 16.** The entire conduit 10 is hollow to define a blood flow conduit 11 providing blood flow communication between open ends **12a, 14a** and **16a.**

[0068] As will be more fully discussed, arms 14 and 16 are adapted to be placed and retained within a lumen of a coronary artery on a downstream side of an occlusion with open ends **14a, 16a** in blood flow communication with the lumen. The anchor arm **12** is adapted to extend through and be retained in a heart wall (e.g., a wall of the left ventricle) with the open end **12a** in blood flow communication with blood within the chamber. When so placed, the conduit 10 defines a surgically-placed conduit establishing direct blood flow from the heart chamber to the artery. By "direct" it is meant that the blood flow does not pass through the aorta as occurs in traditional bypass procedures. The conduit **10** is sufficiently rigid such that it defines an open blood flow path during both diastole and systole.

Optional Forward Flow Bias

[0069] While unobstructed back flow is preferred, partially restricted back flow can be provided. As will be more fully described, back flow can be controlled by the geometry of the conduit. The following describes a presently less preferred alternative principle for controlling back flow.

[0070] **FIG. 2B** illustrates use of an optional bi-directional flow regulator **22** within the conduit **10** and positioned in anchor arm **12.** The bi-directional flow regulator **22** permits unimpeded flow in the direction of arrow **A** (i.e., from open end **12a** to open ends **14a, 16a**) while permitting a reduced (but not blocked) reverse flow.

[0071] **FIG. 2C** illustrates the use of a first bi-directional flow regulator **22** as well as a second bi-directional flow regulator **26** in arm **16** near the open end **16a** of the apparatus. The second bi-directional flow regulator **26** permits unimpeded blood flow in the direction of arrow **B.** The second bi-directional flow regulator **26** is used to permit a reduced (but not zero) back flow of blood in an upstream direction within the coronary artery. For exam-

ple, the coronary artery may not be completely obstructed and may have a reduced flow past an obstruction. The use of the T-conduit **10** with axially aligned arms **14, 16** takes advantage of such reduced flow and supplements such flow with blood through anchor arm **12**. As will be described, the conduit **10** is placed with the arms **14, 16** in the lumen of the artery with opening **16a** positioned on the upstream side (i.e., nearest to, but still downstream of, the obstruction).

[0072] As indicated above, the flow regulator **22** is a bi-directional flow regulator. By this it is meant that the flow regulator **22** does not block flow of blood in any direction. Instead, the flow regulator **22** permits a first or maximum flow rate in one direction and a second or reduced flow rate in a second direction. The flow regulator is schematically illustrated in **FIGS. 9A** through **10C**. In each of these figures, the arrow **A** indicates the direction of blood flow from the left ventricle to the coronary artery.

[0073] **FIGS. 9A** through **9C** illustrate a bi-directional flow regulator **22. FIGS. 10A** through **10C** illustrate an alternative bi-directional flow regulator **22.** The regulator **22** of **FIGS. 9A** throug **9C** shows a butterfly valve **222** mounted in the anchor arm **12** of a rigid conduit **10.** Valve **222** may be pivoted (in response to blood flow in the direction of arrow **A**) between a position with the plate **222** generally parallel to the walls **12** of the conduit **10** as illustrated in **FIG.9A.** The plate **222** can be rotated (in response to blood flow reverse to arrow **A**) to a position angled relative to the walls **12** of the conduit **10** as illustrated in **FIG. 9B. FIG. 9A** may be conveniently referred to as a full flow position. **FIG. 9B** may be conveniently referred to as a reduced flow position. **FIG. 9C** is a cross-section of the conduit **10** when the plate **222** is in the reduced flow position.

[0074] The plate **222** is sized relative to the conduit **10** such that the cross-sectional area of the conduit **10** which remains open is sufficient to permit about 20% of the blood flow (measured volumetrically) to flow back through the conduit **10** in a direction opposite to that of arrow **A** during diastole. As a result, during systole, blood flow from the heart to the coronary artery urges the plate **222** to the full flow position of **FIG. 9A** such blood may flow unobstructed through the device to the coronary artery. During systole, the blood (due to pressure differentials between the coronary artery and the left ventricle) will flow in a direction opposite of that of arrow A causing the plate **222** to rotate to the position of **FIG. 9B** and **9C.** However, even in the reduced flow position, the plate **222** is prevented from moving to a full closed position such that flow through the device is never blocked and instead may proceed with a back flow of about 20% (volumetrically measured) of the normal flow in the direction of **A.**

[0075] **FIGS. 10A** through **10C** show an alternative design of the conduit **10** with the flow regulator **22a** in the form of three leafs **222a, 222b, 222c** which, in response to blood flow from the left ventricle to the coronary artery, open to a full open position shown in **FIG. 10B** and move to a restricted flow position in **FIGS. 10A** and **10C** in response to back flow. The leaves **222a, 222b, 222c** are provided with openings **223** to permit flow through the leaves **222a, 222b, 222c** at all times.

[0076] It is believed that providing a back flow of about 20% (20% being a non-limiting example of a presently anticipated desired back flow rate) of the volumetric anterograde flow is necessary. This is essential because it allows the channel of the conduit **10** and the mechanical elements of the flow regulator **22** to be washed by the retrograde flow. This ensures that no areas of stagnant flow occur. Areas of stagnation, if allowed, could result in clot formation which could result in thrombi occluding the conduit or breaking loose. Thrombi could be carried downstream into the coronary arteries to cause one or more areas of cardiac muscle ischemia (i.e., a myocardial infarction) which could be fatal. Back flow necessary to wash the components can be achieved through either a conduit **10** which has a constant opening through both systole and diastole (i.e., conduit **10** of **FIG. 2A** without the use of a bi-directional flow regulator **22)** or with a device coupled with a bi-directional flow regulator **22** (**FIGS. 2B-2C)** which permits a 20% flow rate back flow during diastole.

L-Shaped Device

[0077] An L-shaped conduit **10' (FIGS. 1A, 1B, 1C)** is used according to the invention to completely bypass the coronary obstruction. An L-shaped conduit **10'** has an anchor arm **12'** with an open end **12a'.** Unlike conduit **10**, conduit **10'** has only one intracoronary arm **14'** perpendicular to arm **12'.** Arm **14'** has an open end **14a'** and conduit **10'** is hollow to define a continuous fluid pathway **11'** from end **12a'** to end **14a'.** In application, arm **14'** is placed within the lumen of an artery. End **14a'** faces downstream from an obstruction. Arm **12'** is placed through the heart wall with end **12a'** in fluid communication with blood within the heart chamber. As illustrated in **FIG. 1B,** the anchor arm **12'** can include a bi-directional flow regulator **22'** similar to bi-directional flow regulator **22** of conduit **10.**

Sizing of the Conduit

[0078] The inner and outer cross-sectional diameters of a coronary artery decreases with the distance from the arterial origin. Eventually, the artery branches into a number of arterioles, which feed the capillary bed of the coronary arterial microcirculation.

[0079] The typical diameter of a lumen of a coronary artery is, in general, species specific; increasing with heart size. In humans, this lumen diameter is dependent upon which artery is being evaluated, but usually ranges from 1.0 to 4 mm in diameter, and decreases with distance from the aortic origin. In the preferred embodiment, the cross-sectional outer diameter of the intracoronary arm **14'** of the device of the present invention

should effectively approximate the diameter of the lumen of the coronary artery being bypassed, at the bypass site. This allows the complete re-approximation of the previously opened superficial wall of the coronary artery during surgical closure, without high suture or staple tension resulting. In the most preferred embodiment, the outer diameter of the intracoronary arm **14'** of the conduit **10'** of the present invention is equal to the diameter of the lumen

[0080] Also, due to smooth muscle relaxation and secondary vascular dilation, the cross-sectional diameter of a lumen of a coronary artery will increase with the oxygen demand of cardiac muscle during times of stress. The cross-sectional inner diameter of the intracoronary arm **14'** of the conduit **10'** of the present invention should effectively approximate that diameter necessary to provide adequate blood flow through the downstream lumen of the conduit to effectively oxygenate the cardiac musculature normally supplied by the microcirculation of the coronary artery. In the preferred embodiment, the cross-sectional inner diameter of the intracoronary arm **14'** of the conduit **10'** of the present invention should effectively approximate that diameter necessary to provide adequate blood flow through the lumen of the device to effectively oxygenate the cardiac musculature normally supplied by the microcirculation of the coronary artery during both times of cardiovascular resting and stress.

[0081] If necessary, an initial approximation of the required cross-sectional outer diameter of the intracoronary arm **14'** of the conduit **10'** of the present invention can be gained by standard radiographic techniques. Also, in the alternative embodiment apparatus when a bi-directional flow regulator **22'** is desired, the operating pressure of the bi-directional flow regulator **22'** (i.e., the pressure at which the flow regulator moves from a reduced back-flow to a full forward flow position) can be determined by the dynamic measurements of coronary artery pressure, blood flow, and heart chamber pressures through selective catheterization with standard techniques. See Minoru Hongo et al., 127(3) AM. HEART J. 545-51 (March 1994).

[0082] During the coronary artery bypass procedure, the most appropriate sizing of the intracoronary arm **14'** of the conduit **10'** of the present invention can be reassessed. This can be accomplished by probing the distal and ,if needed, the proximal aspects of the coronary artery at the chosen bypass site with blunt instruments of known outer diameters. Such sizing by probes is well-known in the literature. To facilitate the effective matching of the external diameter of the intracoronary arms **14'** of the conduit **10'** of the present invention to the lumen **34** of the coronary artery to be bypassed, an assortment of conduits of the present invention of various diameters can be available for the surgeon to select from.

[0083] The anchor arm **12'** is sized to maximize net blood flow from the left ventricle to the coronary artery. Through simulation testing, a counter-intuitive indication is that maximizing the diameter of anchor arm **12'** is not desirable. For example, such simulation assuming diameters of 3.00 mm, 2.25 mm and 1.50 mm for an unrestricted fistula (i.e., without a flow regulator **22'**) suggests that the smaller diameter of 1.50 mm most closely approximates normal coronary blood flow and minimizes back flow thus maximizing net forward flow.

[0084] It is desirable that the anchor arm **12'** protrudes into the heart chamber such that end **12a'** is spaced from the heart wall. This prevents tissue growth over end **12a'.**

[0085] Finally, it will be noted that the anchor arm **12'** defines a longitudinal axis (e.g., axis **X-X** in **FIG. 9A**). The region **15'** of arm **14'** intersects axis **X-X.** The region **15'** acts as a deflection surface to prevent high velocity blood flow from arm **12'** impinging directly upon the coronary artery wall. Instead, the high velocity blood flow impinges upon region **15'** and is directed axially into the coronary artery. As a result, the coronary artery wall covered by region **15'** is protected from damage which would otherwise be caused by the high velocity blood flow and the blood components are transitioned to axial flow with a minimum of cell damaging shear.

[0086] **FIG. 11** shows a device **10"** which is not covered by the present invention as claimed herein but is useful for the understanding of details thereof, like the tapered arm **12"** in this case. The anchor arm **12"** has a longitudinal axis **X'-X'** at a non-orthogonal angle relative to the axis **Y'-Y'** of the coronary arms **14", 16"**. Further, the anchor arm **12"** has a taper. In other words, the arm **12"** is widest at opening **12a".** The taper and angle act to reduce blood flow velocity and to restrict back flow (arrows **B**) while facilitating forward flow (arrow **A'**). Also, the blood in the forward flow **A'** impacts against the deflection region **15"** at an angle to reduce impact of blood cells.

2. The Method of using the device of the Present Invention Using the Open Chest Approach

a. General

[0087] The method of the present invention is suitable for performing a variety of surgical cardiac procedures. The procedures may be performed utilizing an open-chest approach, or through minimally invasive approaches by the creation of access means into the chest, or through percutaneous access utilizing intracoronary and intraventricular catheterization. Dependent on the invasiveness of the approach utilized, the heart can be allowed to pulse normally, be slowed by varying amounts, or stopped completely. A significant period of complete heart stoppage can necessitate the use of supportive cardiopulmonary bypass.

[0088] The method of using the device of the present invention for performing a coronary artery bypass procedure will now be described in detail. The patient who

is to undergo the procedure can be prepared in a conventional manner for cardiac bypass surgery. The patient preparation, anesthesia utilized, and access route to the coronary circulation, will vary depending upon the invasiveness of the specific procedure chosen.

b. Preparation for the Procedure

i. General Preparations

[0089] Standard techniques of general preparation for open-chest surgery in which cardiopulmonary bypass is utilized have been widely reported. *See, e.g.* LUDWIG K. VON SEGESSER, ARTERIAL GRAFTING FOR MYOCARDIAL REVASCULARIZATION (1990). In one embodiment of the methods of using the device of the invention where an open-chest procedure and cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Von Segesser.

[0090] General preparations for open-chest surgery in which cardiopulmonary bypass is not utilized have been published by Buffolo et al., 61 ANN. THORAC. SURG. 63-66(1996). In one of the methods of using the device of the invention where an open-chest procedure without cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Buffolo.

[0091] General preparations for closed-chest surgery, to be performed using thoracoscopy and where cardiopulmonary bypass is utilized, have been outlined by Sterman et al., U.S. Pat. No. 5,452,733 (1995). In one embodiment of the methods of using the device of the present invention where a closed-chest procedure and cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Sterman.

[0092] General preparations for closed-chest surgery to be performed using thoracoscopy, but where cardiopulmonary bypass is not utilized, have been published by Acuff et al., 61 ANN. THORAC. SURG. 135-37 (1996). In one embodiment of the methods of using the device of the present invention where a closed-chest procedure without cardiopulmonary bypass is utilized, the patient can be prepared for surgery as outlined by Acuff.

[0093] General preparations for percutaneous coronary artery bypass grafting utilizing intracoronary and intraventricular catheterization and without cardiopulmonary bypass have been described by Wilk in his afore-mentioned U.S. patents. Preparations can include the sterile scrubbing and draping of at least one groin to permit access to a femoral artery for catheterization of the coronary vasculature and the sterile scrubbing and draping of the right superior anterior chest wall to permit access to the innominate artery for catheterization of the left ventricle. Further suggested preparations can include those outlined by Sterman and Acuff for thoracoscopic surgery with and without cardiopulmonary bypass, respectively.

ii. Anesthesia Prior to and During the Procedure

[0094] Most often, the patient will be placed under general anesthesia prior to the procedure. In one embodiment, standard cardiac operative anesthetic techniques, such as premedication with diazepam, induction with propofol and sufentanil, and maintenance with desflurane can be employed. On occasion, less than general anesthesia can be utilized. Less than general anesthesia is well known in the literature. When the invasiveness of the procedure is minimal, such as when the procedure is to be carried out via intracoronary and intraventricular catheterization. or when the risks of general anesthesia to the individual patient outweighs the risks of less than general anesthesia with regard to the particular procedure planned, less than general anesthesia can be induced. Selective ventilation of the lungs can be achieved through the placement of a double-lumen endobronchial tube which independently provides for the intubation of the left and right main stem bronchi. An intraesophageal probe can be placed to facilitate cardiac monitoring and the synchronization of power to the laser, when deemed useful.

iii. Access to the Heart and Coronary Vasculature for the Procedure

[0095] Following preparation, access to the patient's coronary arterial vasculature can be attained through a variety of techniques, dependent upon the route of access chosen.

[0096] Von Segesser has reported a method of access to the coronary arterial vasculature when utilizing an open-chest approach and cardiopulmonary bypass. In one embodiment, utilizing an open-chest approach with cardiopulmonary bypass, access to the coronary vasculature can be obtained as reported by Von Segesser.

[0097] Buffolo et al. has reported an open-chest approach to the coronary arterial vasculature when performed without cardiopulmonary bypass. *See* Buffolo et al., 61 ANN. THORAC. SURG. 63-66 (1996). In one embodiment utilizing an open-chest approach without cardiopulmonary bypass, access to the coronary vasculature can be obtained as reported by Buffolo.

[0098] Sterman et al. has reported a method of access to the coronary arterial vasculature when a closed-chest approach with cardiopulmonary bypass is utilized. *See* Sterman et al., U.S. Pat. No. 5,452,733 (1995). Sterman positions a plurality of access trocar sheaths along the patient's left and right anterolateral chest wall. These trocar sheaths provide access to the coronary vasculature, and allow the temporary repositioning of the heart to facilitate the performance of the procedure. The repositioning is accomplished utilizing grasping tools introduced through the appropriate trocar sheaths. Visualization during this procedure can be either indirectly via thoracoscopy, or directly via a 'window' placed

in the left middle anterior chest wall by the surgical removal of the fourth rib. Access to the bypass site can therefore be obtained by following the techniques outlined by Sterman. The instruments to be used in the procedure can also be similar to those described by Sterman.

[0099] Acuff et al. has described a method of access to the coronary arterial vasculature when a closed-chest approach without cardiopulmonary bypass is utilized. *See* Acuff et al., 61 ANN. THORAC. SURG. 135-37 (1996). Similar to the techniques of Sterman, Acuff positions a plurality of access trocar sheaths along the patient's left and right anterolateral chest wall. Also similar to Sterman, Acuff surgically establishes an access space, or window in the left anterior chest wall through the removal of the left fourth rib cartilage. The trocar sheaths, in concert with this window, allow the temporary repositioning of the heart, and access to the coronary arterial vasculature. Visualization during this procedure can be either indirectly via thoracoscopy, or directly via the window. Access to the bypass site can therefore be obtained by following the techniques outlined by Acuff. The instruments to be used in the procedure can also be similar to those described by Acuff.

[0100] Access to a chamber of a heart and a coronary artery when the bypass is performed through the percutaneous approach of intracoronary and intraventricular catheterization can be obtained as follows. Access to a coronary artery can be obtained by the introduction of a catheter into the left or right femoral artery through an arterial cut down procedure. The catheter can then be fed retrograde past the descending aorta, through the ascending aorta, and into the coronary artery by standard catheterization techniques. Access to a chamber of the left side of a heart can be obtained by the introduction of a catheter into the innominate artery, also through an arterial cut down procedure. Most prefeably, access to the left ventricle is obtained by the introduction of a catheter into the innominate artery and the advancement of this catheter into the left ventricle. In this case, the catheter is advanced through the ascending aorta, past the aortic valve, and into the left ventricle. Techniques by which the left ventricle is catheterized are well known in the literature.

3. Open Chest Approach

[0101] In the coronary artery bypass graft procedures of using the device of the present invention, a chamber of a heart provides blood to a coronary artery. The method of using the device of the present invention can accomplish this by establishing one or more channels through the wall of a chamber of a heart which lead directly from a chamber of a heart into a coronary artery at a site distal to the narrowing or blockage. The methods of using the device of the invention can achieve the establishment of such a channel or channels through a variety of techniques.

[0102] Referring now to **FIGS. 3, 4, 5, 6, 7,** and **8,** an exemplary open-chest procedure, which may or may not include cardiopulmonary bypass, by which a coronary artery bypass procedure may be accomplished will be described. The open-chest approach affords maximal access to, and visualization of, the coronary vasculature; although at the expense of injury to normal tissue.

[0103] Through the methods of using the device of the present invention, the conduit **10'** of the present invention, which provides blood from a chamber of a heart **43** directly into a coronary artery **30,** is placed. To illustrate the invention, placement of conduit **10'** is discussed. In addition, examples will be limited to the embodiment of the conduit of the invention as illustrated in **FIG. 1A.**

[0104] Preparation for the procedure, and anesthesia prior to and during the procedure, is outlined above.

[0105] First, the chest cavity is entered, and pericardium **52** incised anteriorly, to expose a coronary artery **30** (having an obstruction **34**) to be bypassed. This is illustrated in **Fig. 3.**

[0106] Second, cardiopulmonary bypass may be initiated by a variety of standard techniques as outlined by George Silvay et al., *Cardiopulmonary Bypass for Adult patients: A Survey of Equipment and Techniques*, 9(4) J. CARDIOTHORAC. VASC. ANESTH. 420-24 (August 1995).

[0107] Third, if bypassed, the heart is slowed and/or stopped by a variety of standard techniques. One standard technique is to electrically induce ventricular fibrillation. Another standard technique is warm or cold blood cardioplegia, delivered antegrade or retrograde, and intermittent or continuous, as outlined by Gerald D. Buckberg, *Update on Current Techniques of Myocardial Protection*, 60 ANN. THORAC. SURG. 805-14 (1995).

[0108] Fourth, the heart is inspected and coronary arteries identified. The narrowed or occluded coronary artery **30** can be visually identified, and an appropriate site distal or downstream from the occlusion **34** chosen.

[0109] Fifth, blood flow through the target coronary artery **30** is halted by standard techniques. For example, standard techniques include clamping the aorta above the coronary ostia with an arterial clamp. Alternatively, in the beating heart procedure, the flow of blood within the coronary artery **30** can be halted by forming a loop around the artery **30** with suture either proximally, or both proximally and distally, and applying appropriate tension on the suture or sutures, or tying the suture or sutures.

[0110] Sixth, depending on the degree of exposure deemed necessary, the epicardium overlying the coronary artery at the selected bypass site is incised. This exposure can facilitate locating the lumen of the coronary artery **30** via palpation.

[0111] Seventh, as shown in **FIG. 4,** the superficial wall **36** of the coronary artery **30** is longitudinally incised by standard techniques, such as incision with a scalpel. electrosurgical cutting device, or similar tool; taking care not to damage the deep wall of the artery. This initial

incision can be lengthened, if necessary, to accommodate the intracoronary arms **14'** using standard tools such as fine angled scissors.

[0112] Eighth, a channel **50** is initiated into the deep coronary arterial wall **40** and through the musculature **42** of a chamber of a heart. In the preferred embodiment, the chamber of a heart is the left ventricular chamber of the heart. The channel **50** can be initiated by standard techniques such as awl punching, incising, use of a laser, or the like. The channel **50** is then extended into the chamber of a heart, in this case the left ventricle **44**, by standard techniques (such as punching with a trocar **46**, incising with a scalpel blade, electrosurgical cutting with an electrosurgical cutting tool, laser or radio frequency ablation, blunt dissection, etc.).

[0113] Ninth, once a channel extending through the entire thickness of a wall **42** of a chamber of a heart is formed, it can be systematically sized by the passage of standard probes.

[0114] Tenth, through palpation, inspection, and probing of the distal and proximal coronary artery lumen **48**, a conduit **10'** of appropriate dimensions is selected, as outlined above.

[0115] Eleventh, as illustrated in **FIGS. 6** and **7**, the anchor arm **12'** is inserted into the formed channel **50**. The intracoronary arm **14'** is then seated within the lumen **48** of the coronary artery **30.**

[0116] Twelfth, as shown in **FIG. 8**, the longitudinal incision **38** previously incised in the anterior wall **36** of the coronary artery **30** is surgically re-approximated. The re-approximation can be performed by a number of conventional techniques, including suturing **52**, laser welding, microstapling, and the like.

[0117] Thirteenth, the clamps or sutures closing off blood flow to the coronary artery are released.

[0118] Fourteenth, contractions of the heart, if previously stopped, are reinitiated by standard electrostimulation or the reversal of cardioplegia and the patient is slowly weaned from cardiopulmonary bypass by standard techniques.

[0119] Fifteenth, the pericardium, sternum, and overlying skin of the chest is re-approximated and surgically closed by standard, conventional techniques.

[0120] Sixteenth, anesthesia is reversed and the patient revived by standard techniques.

D. Closed Chest Approach

1. The Apparatus of the Present Invention for Use in the Closed Chest Approach

[0121] A closed chest approach according to the method of using the device of the present invention may use the conduit **10'** as described above. Such a procedure will now be described.

2. The Method of using the device of the Present Invention Using the Closed Chest Approach

[0122] An exemplary closed-chest procedure, without cardiopulmonary bypass, by which a coronary artery bypass may be accomplished will now be described. The closed-chest approach is less invasive than the open-chest approach, although providing the surgeon with somewhat poorer visualization and limited direct access to both the chambers of the heart and coronary artery bypass site.

[0123] Preparation for the procedure, and anesthesia prior to and during the procedure, is outlined above.

[0124] First, a plurality of access trocar sheaths is positioned anterior and laterally along the left and right chest walls as outlined by Acuff et al.

[0125] Second, a space in the left low anterior chest wall may be formed by removal of the fourth rib cartilage, as outlined by Acuff et al. In this embodiment, the heart and coronary artery can be both directly viewed via this space or window, as well as indirectly visualized via a thoracoscope.

[0126] Third, a standard pericardiotomy is performed using a scalpel or electrosurgical cutting tool introduced through the left lateral chest trocar sheaths while viewing under thoroacoscopy. The pericardium can be excised and either spread open, or removed from the thoracic cavity as outlined by Acuff et al.

[0127] Fourth, if necessary, the heart can be rotated within the mediastinum. Direct access and visualization through the formed chest wall space can require rotation of the heart. Rotation of the heart can be accomplished by the grasping of the heart by tools inserted through access trocar sheaths located along the left and right chest wall as described by Sterman et al. Alternatively, traction on sutures placed in the pericardium can distract the heart allowing appropriate direct visualization of the area to be bypassed as described by Acuff et al. In another alternative procedure, the heart can be accessed from the patient's back with an endoscope for implantation of the stent in the posterior vascular beds which are not currently accessible by minimally invasive techniques.

[0128] Fifth, once the coronary artery to be bypassed is identified and well-visualized; snare sutures of 5-0 polypropylene are placed at least proximally to the target area as described by Acuff et al.

[0129] Sixth, the heart rate can be pharmacologically slowed to approximately 40 beats/minute to minimize motion within the operative field as described by Acuff et. al. Nitroglycerin and heparin can also be administered to reduce cardiac ischemia and prevent clotting respectively as outlined by Acuff et al.

[0130] Because cardiopulmonary bypass is omitted in this embodiment, intermittent coronary artery occlusion to induce ischemic preconditioning, as well as transesophageal echocardiography to review cardiac wall motion changes, can be utilized as described by Acuff

et al. The epicardium can be incised over the area selected for bypass and the anterior surface of the artery cleared under direct visualization through the space or window, or via remote instruments inserted through the trocar sheaths under thoracoscopic guidance.

[0131] Seventh, in situations where the coronary artery can be directly viewed, the lumen **48** of the coronary artery is identified by palpation. Either under direct visualization, or under thoracoscopic guidance and using instruments manipulated through the trocar sheaths, the superficial wall **36** of the coronary artery is then longitudinally opened. As above, care is taken to leave the deep wall **40** of the artery undamaged. The incision **38** can be enlarged, as necessary, to accommodate the intracoronary arm **14'** of the conduit **10'** using fine angled scissors. This enlargement can be performed with standard surgical scissors under direct viewing through the window, or via other surgical instruments remotely manipulated following their insertion through the trocar sheaths.

[0132] Eighth, a channel **50** through the heart wall is initiated by incising or laser ablating into the deep wall **40** of the coronary artery. This also can be performed by standard surgical tools under direct viewing, or by the remote manipulation of specialized instruments introduced through the trocar sheaths and viewed thoracoscopically. The channel **50** is then extended through the deep coronary arterial wall **40**, through underlying cardiac musculature **42**, and into the underlying chamber of the heart **44** by incising with a scalpel or electrosurgical cutting blade, laser ablation, blunt dissection, or the like. Preferably, a chamber of a heart **44** is one of the two chambers of the left side of the heart. Most preferably, a chamber of a heart **44** is the left ventricle.

[0133] Ninth, the channel **50** extending through the entire thickness of a muscular wall **42** can be systematically sized by the passage of standard measuring probes. These standard measuring probes, with fixed and known tip diameters, can be similarly used to size and determine the proximal and distal patency of the coronary artery being bypassed.

[0134] Tenth, through direct and/or thoracoscopic inspection of the coronary artery lumen **48**, or by probing as outlined above, an appropriately dimensioned conduit **10'** of the present invention is selected. As in the case of the open-chest approach (outlined above), an array of conduits **10'** of various sizes can be available for the operation.

[0135] Eleventh, either under direct control and visualization, or by indirect manipulation and thoracoscopic viewing, the anchoring arm **12'** of the conduit **10'** of the invention is inserted into the formed channel **50**. By similar techniques the remaining intracoronary arm **14'** of the conduit **10'** is seated within the lumen **48** of the coronary artery **30** being bypassed. In one case where the procedure is performed under thoracoscopic viewing, the conduit **10'** can be introduced into the cardiac cavity through the space or window previously formed within the anterior inferior aspect of the left chest wall. In this case, the conduit **10'** can be grasped, once introduced into the chest cavity, by surgical instruments inserted through the trocar sheaths and remotely manipulated into position. In this manner the anchor arm **12'** of the conduit **10'** is then inserted into the channel formed **50** via the remote manipulation of these instruments.

[0136] Twelfth, the incision present in the superficial wall **38** of the coronary artery **30** is closed by conventional surgical techniques such as suturing, laser welding, microstapling, and the like. When closure is by indirect thoracoscopic versus direct viewing, suturing, laser welding, microstapling and the like can be accomplished by utilizing surgical instruments remotely manipulated following their introduction through the trocar sheaths.

[0137] Thirteenth, upon completion of placement of the conduit **10'** of the present invention, the heart, if rotated, can be returned to its normal orientation.

[0138] Fourteenth, all heart manipulating devices are removed from the chest cavity.

[0139] Fifteenth, contractions of the heart can be allowed to return to their normal resting rate by the discontinuation of intravenous esmolol and diltiazem, if utilized.

[0140] Sixteenth, the pericardium **52** is partially or completely re-approximated. An external drain can be placed inside the pericardium, as needed, as described by Acuff et al.

[0141] Seventeenth, the trocar sheaths are removed, and all thoracic punctures surgically repaired in a conventional manner.

[0142] Eighteenth, anesthesia is reversed and the patient revived by standard techniques.

Claims

1. An apparatus for use in a coronary artery bypass procedure, said apparatus comprising:

   (a) a substantially rigid L-shaped conduit 10' having a first arm 12' with a first end suitable for insertion into and retention within a wall of a heart chamber containing oxygenated blood with said first end in blood flow communication with blood contained within said chamber;
   (b) said conduit having a second arm 14' with a second end suitable for insertion into and retention within said coronary artery with said second end in blood flow communication with a lumen of said coronary artery;
   (c) said conduit being suitable for, in use, defining and maintaining an open blood flow pathway from the first end to the second end during contraction of the heart, the configuration and sizes of the conduit being such that when the said first arm is inserted into said heart chamber

so that its end is in blood flow communication with blood contained within said chamber, the second arm 14' can extend into a neighbouring coronary artery.

2. An apparatus according to claim 1, in which the first and second arm have longitudinal axes that are perpendicular.

3. An apparatus according to claim 1, in which the first and second arms 12', 14' have longitudinal axes which have an angle greater than 90° between them.

4. An apparatus according to claim 1, in which said conduit 10' has a geometry selected to bias forward flow of blood from said first end toward said second end while not blocking blood flow from said second end toward said first end.

5. An apparatus according to claim 4, in which the conduit 10' has a narrower internal diameter at the second end than at the first end.

6. An apparatus according to claim 4 or claim 5, in which the internal diameter of the conduit 10' tapers from the first end to the second end.

7. An apparatus according to claim 1 further comprising a bi-directional flow regulator 22.

8. An apparatus according to any preceding claim in which the cross sectional outer diameter of the second arm is from 1 to 4 mm.

9. An apparatus according to any preceding claim, in which the conduit is sized for the first end to penetrate beyond a wall of the heart chamber and into said heart chamber in use.

10. An apparatus according to claim 9, in which the first end is dimensioned to penetrate from 1 to 3 mm into the heart chamber in use.

11. A kit comprising a plurality of apparatus according to any preceding claim, each apparatus having a different external diameter.

12. A kit according to claim 11, in which each of the apparatus have a second arm having a different external diameter of from 1 and 4 mm.

Patentansprüche

1. Vorrichtung zur Verwendung in einem Koronararterienpypasseingriff, wobei die Vorrichtung aufweist:

(a) eine im wesentlichen feste L-förmige Leitung (10') mit einem ersten Arm (12') mit einem ersten Ende, das geeignet ist, in eine Wand einer Herzkammer eingesetzt und darin gehalten zu werden, die sauerstoffreiches Blut enthält, wobei das erste Ende in einer Blutflußkommunikation mit dem Blut steht, das in dieser Kammer enthalten ist.

(b) wobei diese Leitung einen zweiten Arm (14') hat, der dazu dient, in die Koronararterie eingesetzt und darin gehalten zu werden, wobei das zweite Ende in Blutflußkommunikation mit einem Lumen der Koronararterie steht.

(c) wobei diese Leitung dazu dient, bei Gebrauch einen offenen Blutflußweg von einem ersten Ende zu einem zweiten Ende während der Kontraktion des Herzes zu bilden und zu erhalten, wobei die Konfiguration und die Abmessungen der Leitung derartig sind, daß, wenn der erste Arm in die Herzkammer eingesetzt ist, so daß sein Ende in Blutflußkommunikation mit dem Blut steht, das in dieser Kammer enthalten ist, der zweite Arm (14') sich in eine benachbarte Koronararterie erstrecken kann.

2. Vorrichtung nach Anspruch 1, wobei der erste und zweite Arm Längsachsen haben, die senkrecht sind.

3. Vorrichtung nach Anspruch 1, wobei der erste und zweite Arm (12', 14') Längsachsen haben, die zwischen sich einen Winkel haben, der größer als 90° ist.

4. Vorrichtung nach Anspruch 1, wobei die Leitung (10') eine Geometrie hat, die so gewählt ist, daß sie einen Vorwärtsblutfluß von dem ersten Ende in Richtung des zweiten Endes bevorzugt, wobei der Blutfluß von dem zweiten Ende in Richtung des ersten Endes nicht blockiert wird.

5. Vorrichtung nach Anspruch 4, wobei die Leitung (10') am zweiten Ende einen kleineren Innendurchmesser hat als am ersten Ende.

6. Vorrichtung nach Anspruch 4 oder 5, wobei sich der Innendurchmesser der Leitung (10') vom ersten Ende zum zweiten Ende verändert.

7. Vorrichtung nach Anspruch 1, ferner mit einem bidirektionalen Durchflußregler (22).

8. Vorrichtung nach einem der vorhergehenden Ansprüche, wobei der Außendurchmesser des zweiten Arms im Querschnitt 1 bis 4 mm ist.

9. Vorrichtung nach einem der vorhergehenden An-

sprüche, wobei die Leitung so bemessen ist, daß das erste Ende bei Gebrauch durch eine Wand der Herzkammer hindurch und in die Herzkammer eindringt.

10. Vorrichtung nach Anspruch 9, wobei das erste Ende so dimensioniert ist, daß es bei Gebrauch 1 bis 3 mm in die Herzkammer eindringt.

11. Zubehörsatz mit mehreren Vorrichtungen nach einem der vorhergehenden Ansprüche, wobei jede Vorrichtung einen anderen Außendurchmesser hat.

12. Zubehörsatz nach Anspruch 11, wobei jede der Vorrichtungen einen zweiten Arm mit einem anderen Außendurchmesser von 1 bis 4 mm hat.

Revendications

1. Appareil destiné à être utilisé dans une procédure de dérivation d'artère coronaire, ledit appareil comprenant :

   (a) un conduit en L sensiblement rigide (10') comportant une première branche (12') dont une première extrémité est adaptée pour être insérée et retenue dans une paroi d'une chambre d'un coeur contenant du sang oxygéné, ladite première extrémité étant en communication de flux sanguin avec le sang contenu dans ladite chambre ;
   (b) ledit conduit comportant une deuxième branche (14') dont une deuxième extrémité est adaptée pour être insérée et retenue dans ladite artère coronaire, ladite deuxième extrémité étant en communication de flux sanguin avec un lumen de ladite artère coronaire ;
   (c) ledit conduit étant adapté pour, en service, définir et maintenir un passage de flux sanguin ouvert de la première extrémité jusqu'à la deuxième extrémité pendant la contraction du coeur, la configuration et les dimensions du conduit étant telles que, lorsque ladite première branche est insérée dans ladite chambre du coeur de sorte que son extrémité soit en communication de flux sanguin avec le sang contenu dans ladite chambre, la deuxième branche (14') puisse s'étendre dans une artère coronaire voisine.

2. Appareil selon la revendication 1, dans lequel les première et deuxième branches ont des axes longitudinaux perpendiculaires.

3. Appareil selon la revendication 1, dans lequel les première et deuxième branches (12', 14') ont des axes longitudinaux qui forment entre eux un angle supérieur à 90°.

4. Appareil selon la revendication 1, dans lequel la géométrie dudit conduit (10') est sélectionnée pour diriger le flux sanguin depuis ladite première extrémité vers ladite deuxième extrémité sans bloquer le flux sanguin depuis ladite deuxième extrémité vers ladite première extrémité.

5. Appareil selon la revendication 4, dans lequel le conduit (10') a un diamètre interne plus étroit au niveau de la deuxième extrémité qu'au niveau de la première extrémité.

6. Appareil selon la revendication 4 ou la revendication 5, dans lequel le diamètre interne du conduit (10') diminue depuis la première extrémité jusqu'à la deuxième extrémité.

7. Appareil selon la revendication 1, comprenant, en outre, un régulateur de débit bidirectionnel (22).

8. Appareil selon l'une quelconque des revendications précédentes, dans lequel le diamètre extérieur de la section de la deuxième branche est de 1 à 4 mm.

9. Appareil selon l'une quelconque des revendications précédentes, dans lequel le conduit est dimensionné pour que la première extrémité pénètre au-delà d'une paroi de la chambre du coeur et dans ladite chambre du coeur en service.

10. Appareil selon la revendication 9, dans lequel la première extrémité est dimensionnée de manière à pénétrer de 1 à 3 mm dans la chambre du coeur en service.

11. Kit comprenant une pluralité d'appareils selon l'une quelconque des revendications précédentes, chaque appareil ayant un diamètre externe différent.

12. Kit selon la revendication 11, dans lequel chacun des appareils comporte une deuxième branche ayant un diamètre externe différent de 1 à 4 mm.

Fig.1A

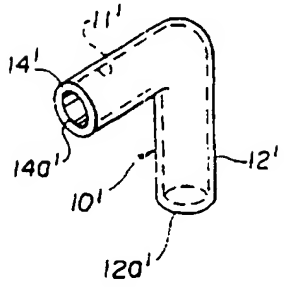


Fig.1B

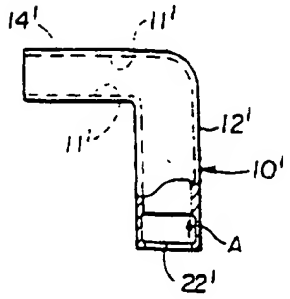


Fig.2A

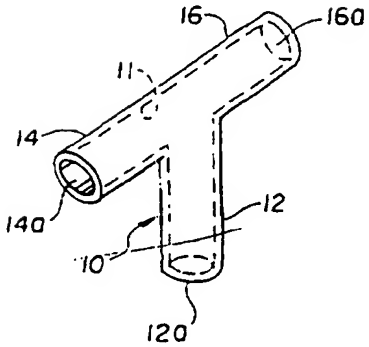


Fig.2B

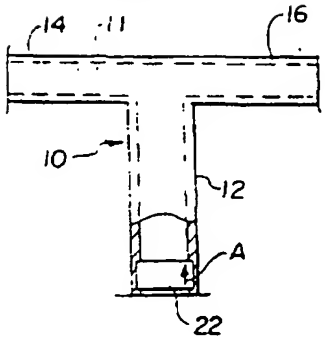


Fig.2C

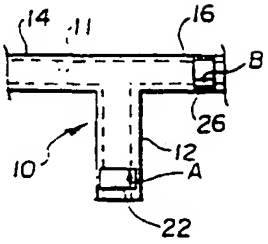


Fig. 3

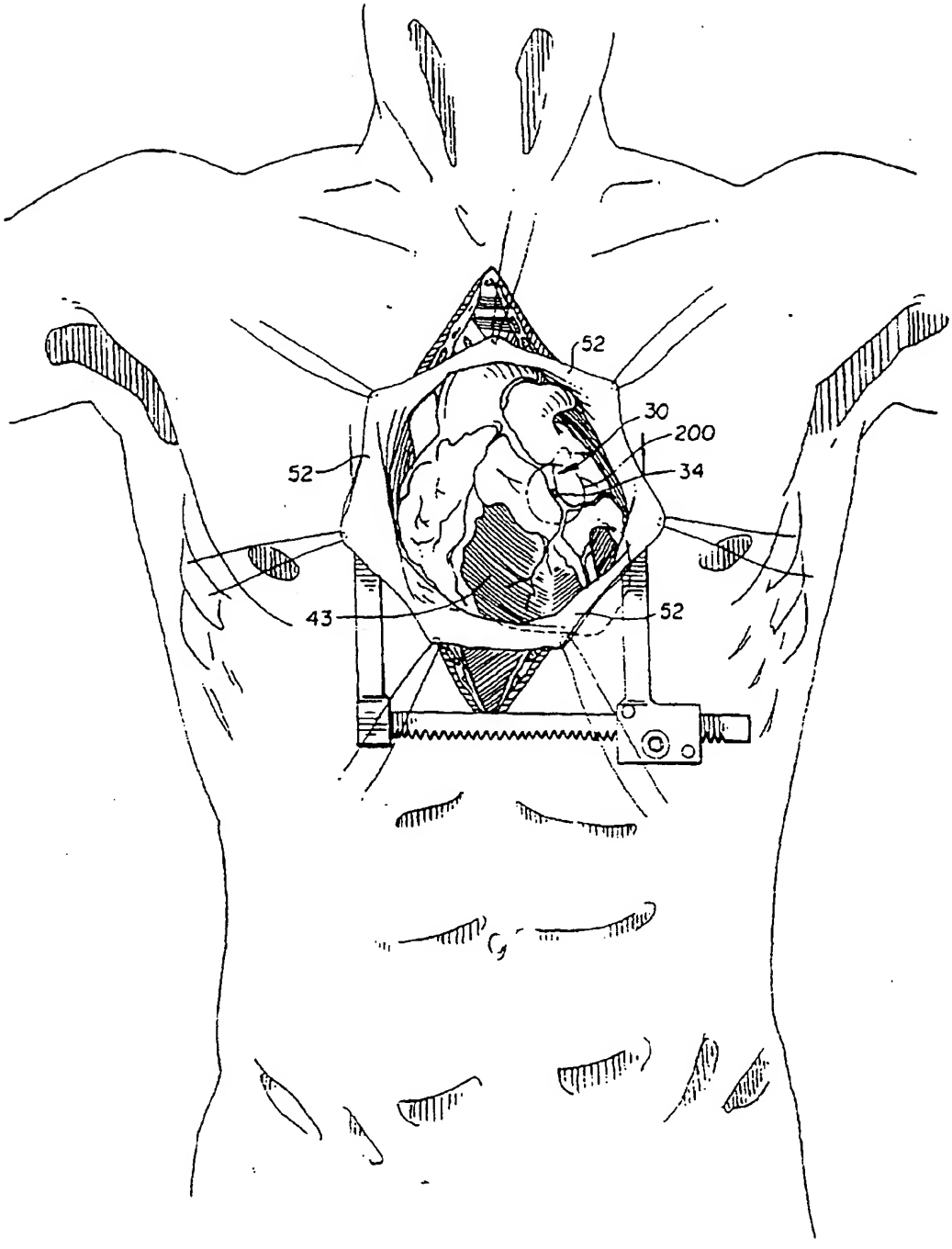


Fig. 4

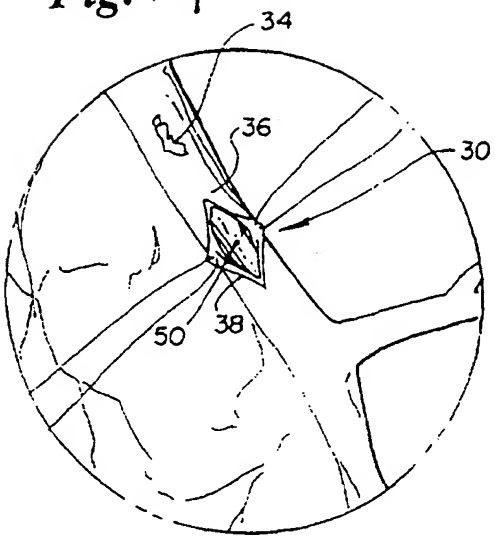


Fig. 5

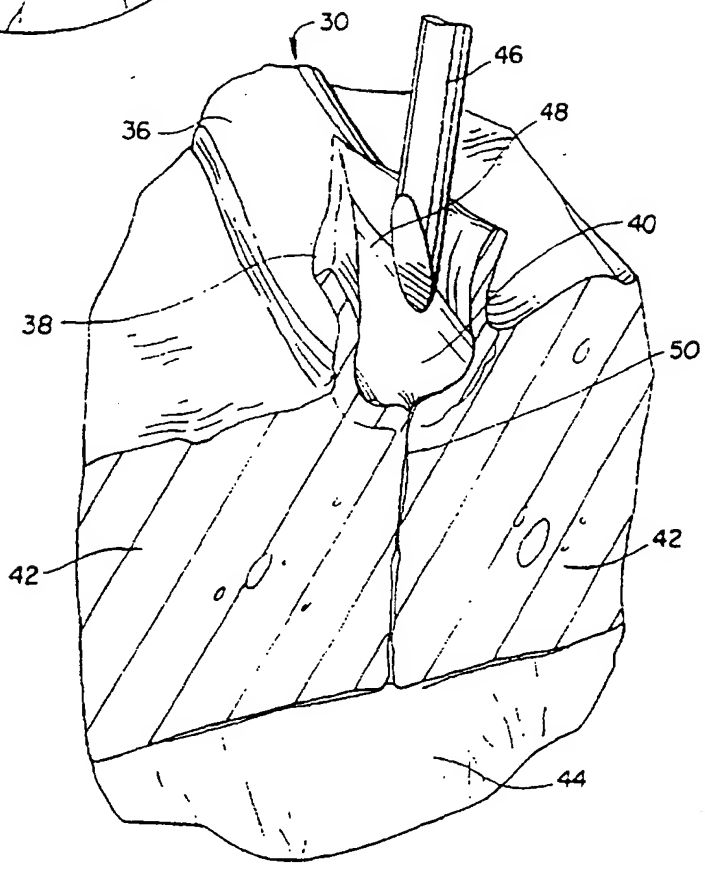


Fig. 6

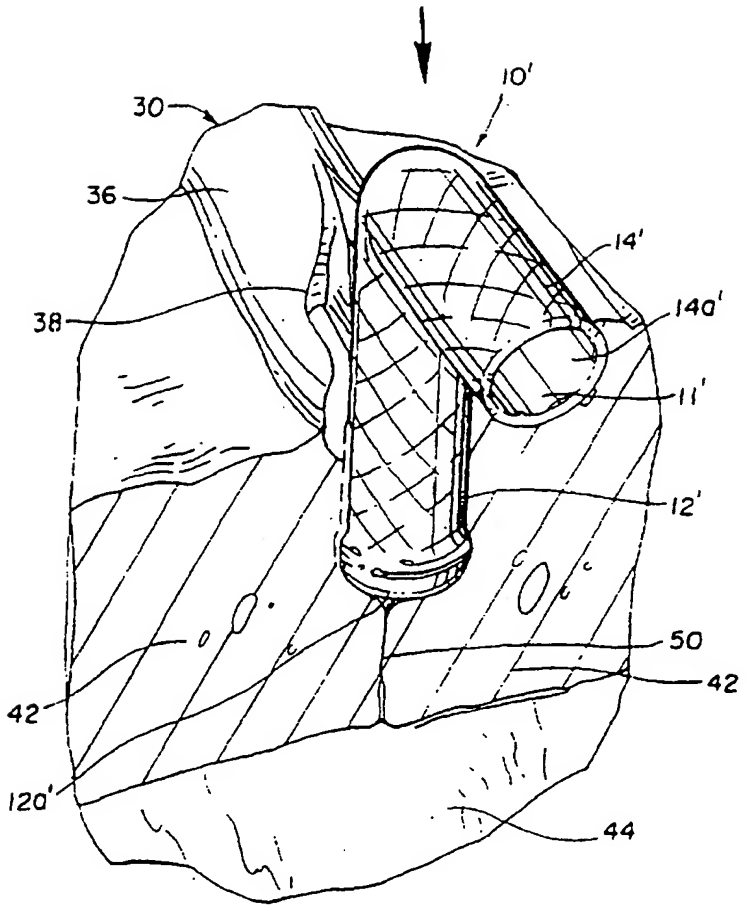


Fig. 7

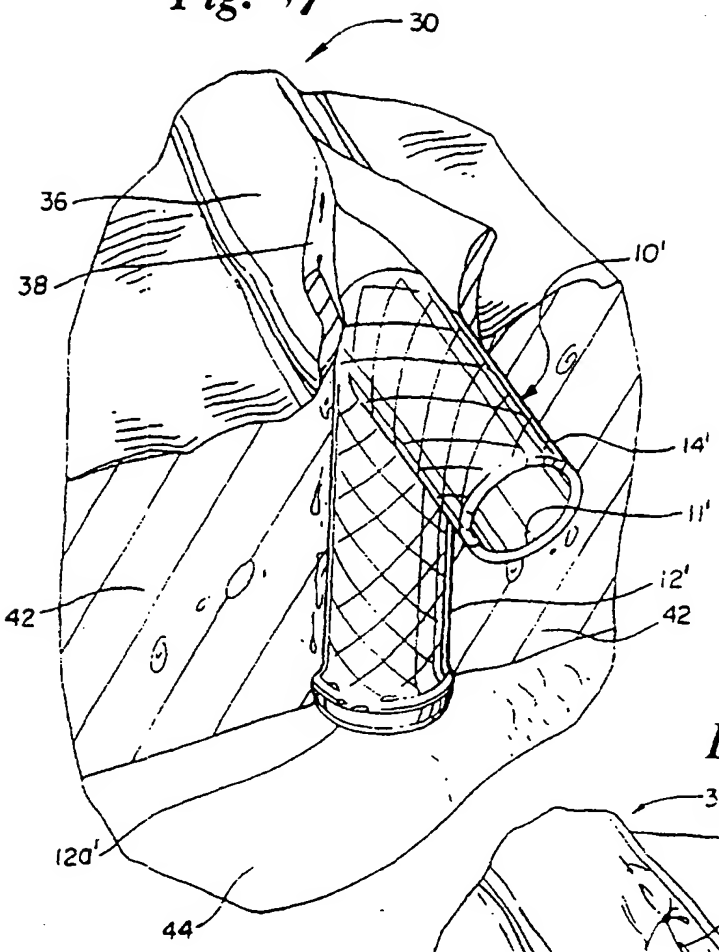


Fig. 8

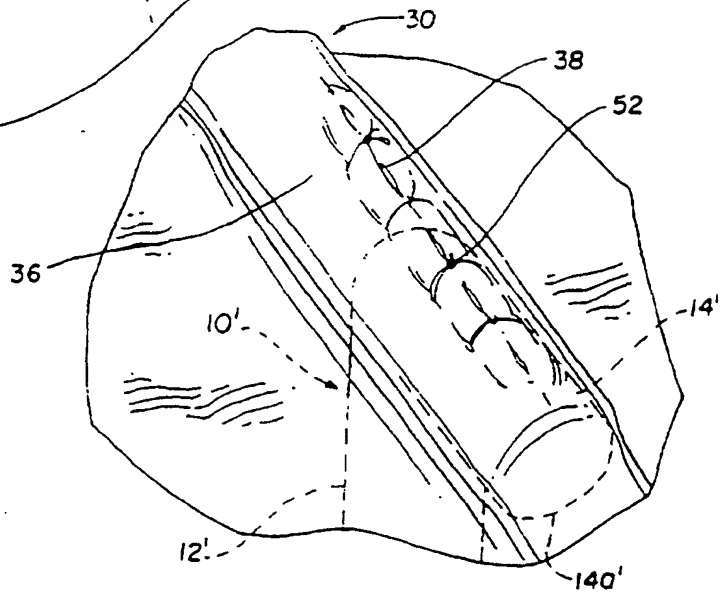


FIG. 9A

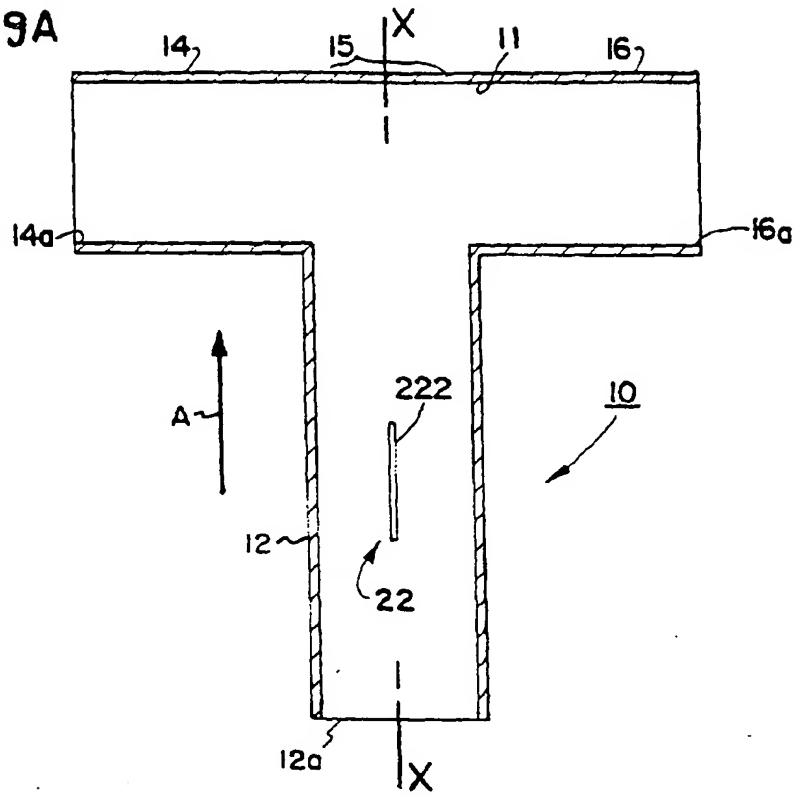

14
15
X
11
16
14a
16a
A
222
10
12
22
12a
X

FIG. 9B

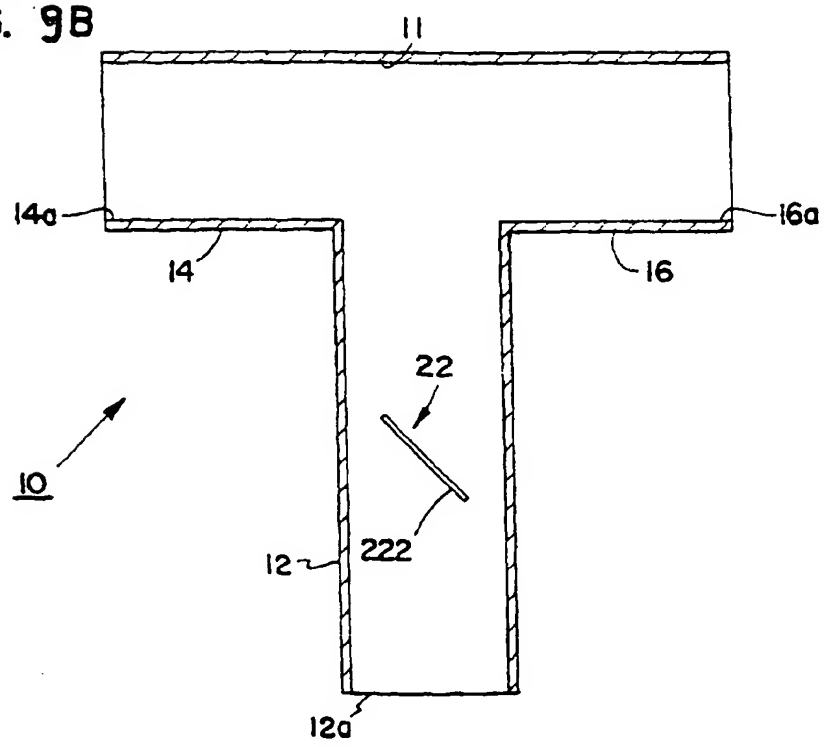

11
14a
16a
14
16
22
10
222
12
12a

FIG. 9C

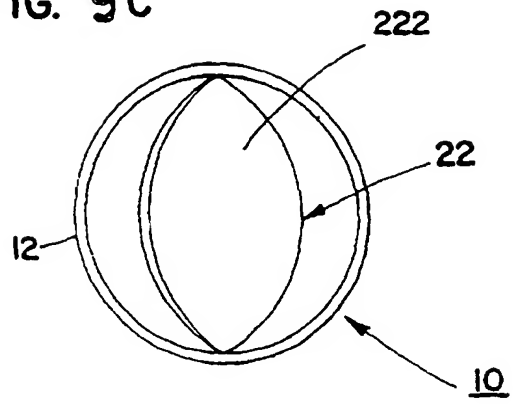


FIG. 10C

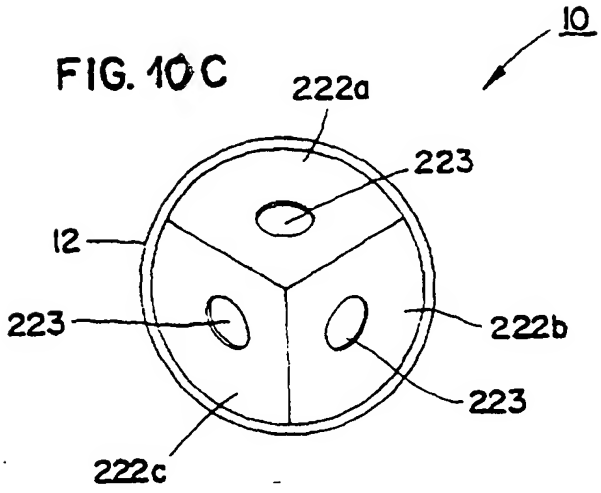


FIG. 10A

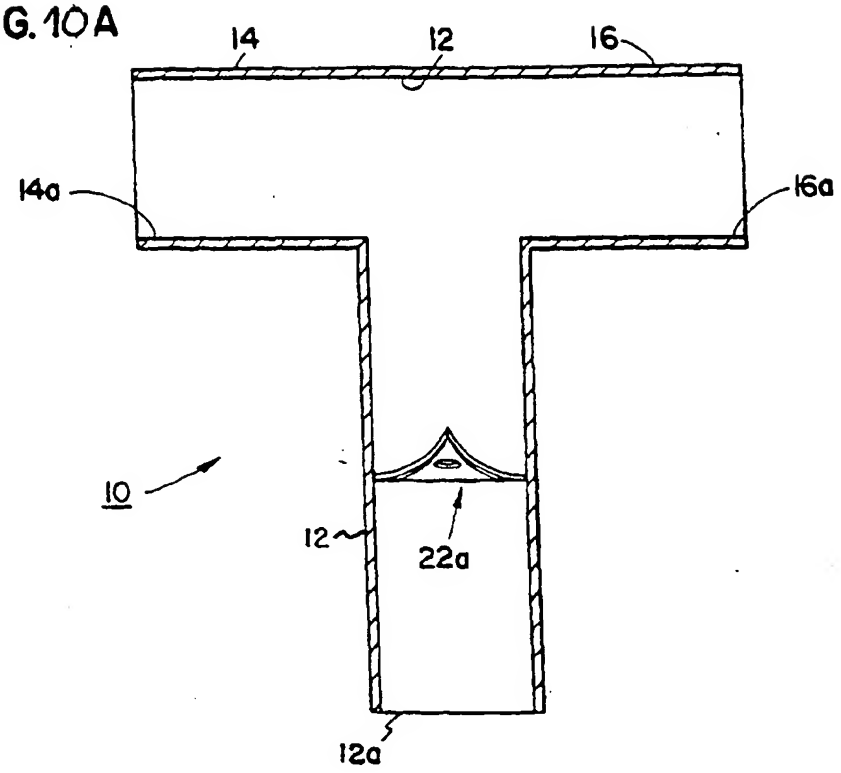
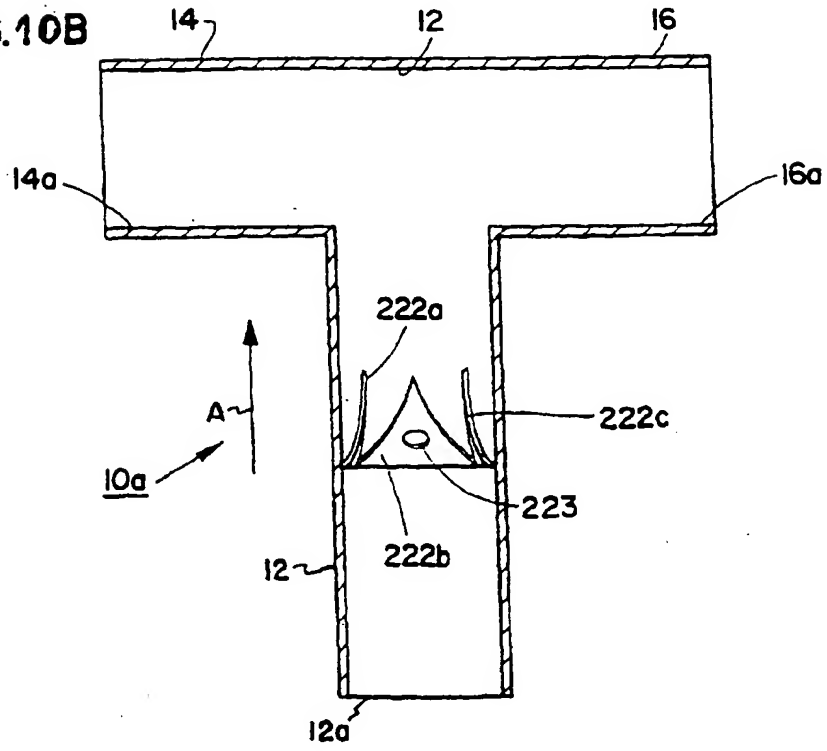


FIG. 10B



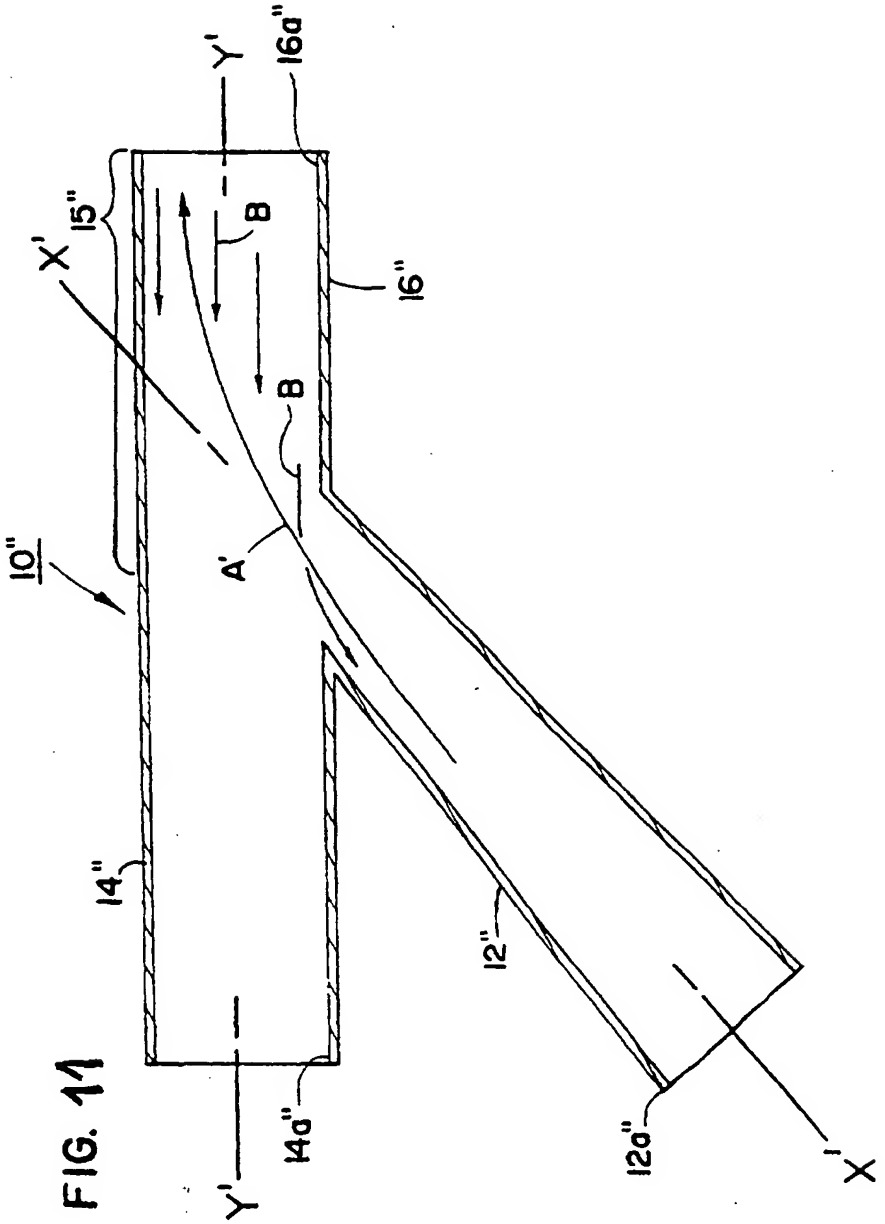


FIG. 11

FIG. 12

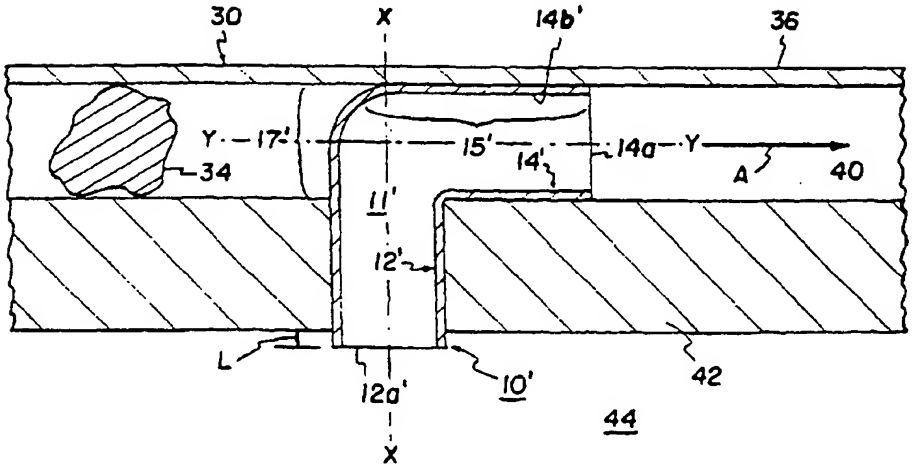

30
X
14b'
36
Y
17'
15'
14'
14a
Y
A
40
34
11'
12'
L
12a'
10'
42
44
X

FIG. 13

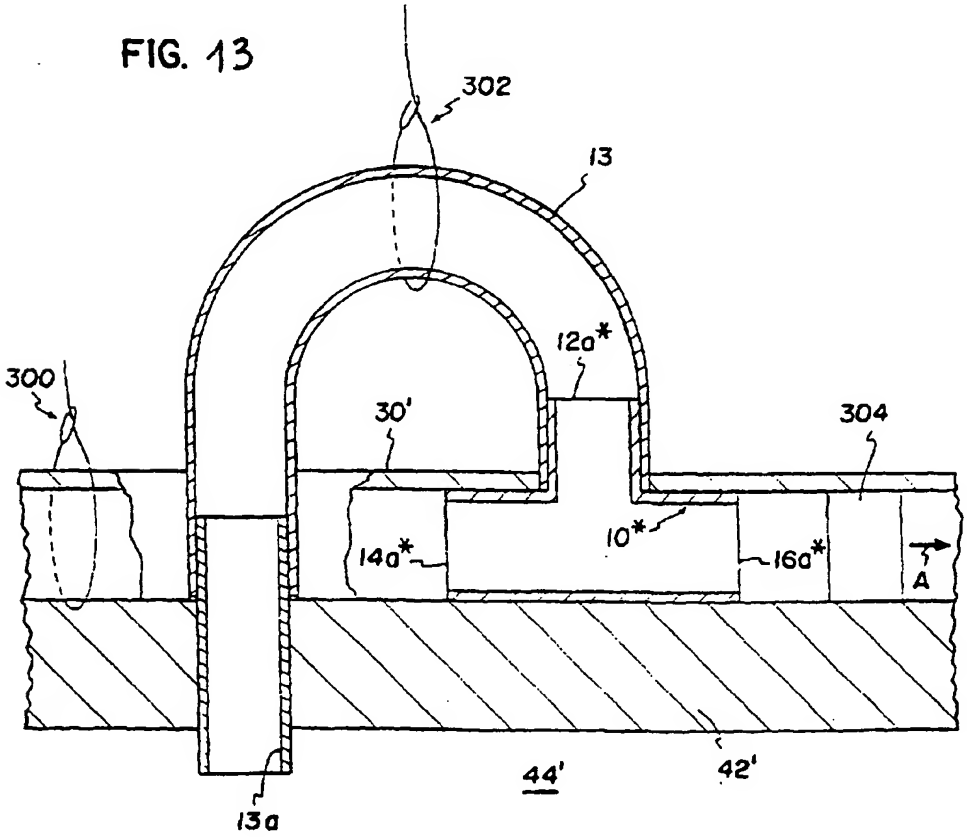

302
13
12a*
300
30'
304
14a*
10*
16a*
A
44'
42'
13a

FIG. 14